UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/988,728	11/16/2001	Gowri Pyapali Selvan	111465.132(PROV-104/118/2	8956

20995 7590 11/02/2005

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER
LUM, LEON YUN BON

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/988,728	SELVAN, GOWRI PYAPALI	
	Examiner	Art Unit	
	Leon Y. Lum	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22 and 30-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22 and 30-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed 19 October 2005 is acknowledged and has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-22 and 30-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 1 recites the limitation "the specific immunotyping assay to be conducted" in lines 14-16. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section

> 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-9, 12-15, 17-21, 30-31, and 34-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Sheppard, Jr. et al (USP 6,143,247).

In the instant claims, Sheppard, Jr. et al reference teaches the steps of applying a sample to a detection or cell accumulation chamber of a platform (i.e. providing a sample of cells in a chamber in a disc), wherein the term "platform" is intended to encompass any solid support structure providing a surface or comprising a chamber that can be treated to comprise a specific binding reagent (i.e. chamber including at least one capture zone with a capture agent), wherein a binding chamber 24 is connected to a sample inlet port 21 (i.e. inlet port), and wherein the platform also includes air outlet ports (i.e. vent port). See column 8, lines 14-25; column 10, lines 15-18; column 13, line 56 to column 14, line 5; column 14, lines 6-7; and Figure 2. In addition, Sheppard, Jr. et al teach that the detection system can comprise a component of a device manipulating the platform, preferably comprising an optical detecting means and that the disk can be loaded and spun (i.e. loading the disc into an optical reader; rotating the disc). See column 14, lines 61-63; column 26, lines 55-56. In addition, Sheppard, Jr. et al also teach the steps of actuating means for positioning a light source on the surface of the platform and having photodetectors to optimally detect optical absorbance/transmittance or other optical signals (i.e. directing an incident beam of electromagnetic radiation to the capture zone; detecting a beam of electromagnetic radiation formed after interacting with the disc at the capture zone), which are

processed and translated into data including the number of cells on the platform (i.e. generating an output signal indicative of at least a portion of the at least one beam relating to captured cells; analyzing the at least a portion of the output signal to extract therefrom information relating to the number of cells captured at the capture zone; generating a count of the number of cells), and wherein the device can also be provided having an interface with an integrated computer having image-processing features. See column 21, lines 57-67 and column 31, lines 31-39. Sheppard, Jr. et al also teach that controllers fabricated directly onto a platform use data encoded in the disk's data-carrying surface can be used to control the rotation drive motor (i.e. information for controlling the rotation of the disc) and analysis (i.e. information for processing the specific immunotyping assay to be conducted). See column 26, line 63 to column 27, line 11; and column 27, lines 24-27. In addition, Sheppard, Jr. et al teach multiple detectors (i.e. a detector and a trigger sensor) to perform optical functions including detecting multiple beams focused on either the main beam illuminating cells on an upper surface 14 or secondary beams illuminating reflective regions 15 (i.e. trigger marks) used for tracking purposes (i.e. use of detector at the at least one capture zone; detecting trigger information by use of the trigger sensor from a disc location that is separate from the at least one capture zone; generating a trigger signal in responses to the detected trigger information; a first and second beam; trigger sensor comprise a detector responsive to the first beam). See column 8, lines 9-14; column 11, line 40; column 12, lines 15-35; and Figure 1D. Furthermore, Sheppard, Jr. et al reference teaches that the surface or detection chamber can be treated to provide a two-

dimensional array or pattern, wherein certain areas on the surface or detection chamber are treated with said specific binding reagent and others are not in a recognizable manner such that each of a multiplicity of specific binding reagents of distinct specificity are applied to different areas or regions of a surface or detection chamber of the platform, thereby providing a pattern of distinct specific binding reagents on the platform, including alternating strips, checks, concentric circles, and a "bar code", and wherein there can be multiple detection chambers arrayed serially. See column 9, lines 5-7; column 10, lines 59-64; column 11, lines 1-25; and Figure 4E.

Although Sheppard, Jr. et al reference does not explicitly teach the limitations of rotating the disc "so as to capture different cell types in different capture zones" and counting captured cells "in each of the at least one capture zones", the instant reference teaches the limitations by disclosing disc rotation, cell counting, and a series of separate binding reagent arrangements, as stated above. The instant reference discloses a multiplicity of specific binding reagents in different areas of a detection chamber, the arrangement of a "bar code" or concentric circles in a detection chamber, and the placement of multiple detection chambers in a serial array. Since Sheppard, Jr. et al reference teaches the rotation of the disc, centrifugal force would move sample fluid in a serial fashion, causing the fluid to enter the serially arrayed detection chambers in a sequential manner. Multiple cell types in a fluid sample would be captured by different specific binding reagents in different regions of the disc, either in separate detection chambers, or in different regions of the "bar code" or concentric circles within a

detection chamber, thereby separating different cell types into different capture zones and allowing counting of the cells in each of the zones.

In regards to claim 2, Sheppard, Jr. et al teach that the platform surface is internal to the disc and is enclosed (i.e. bounded on opposite sides) by a top layer (i.e. cap) and a bottom layer (i.e. substrate). See Figures 5A-E. In reference to the figures, the focus of the light from the light source 54 is on the surface of the chamber where the cells are located (see column 14, lines 39-58), and therefore the surface can be considered as part of the substrate, indicated above as the bottom layer. The top layer can be considered a cap since it is superior to the chamber space and opposite the substrate.

In regards to claim 3, Sheppard, Jr. et al teach that platforms can comprise a reflective surface (i.e. reflective layer) and the detector and the light source are positioned on the same side of the platform. See column 24, lines 28-31. A reflective surface inherently reflects light if the light is not attenuated or absorbed by a substance, including a cell on the disc. Therefore, although the reference does not explicitly teach the limitation where "light directed to the capture zone and not striking a cell is reflected", one of ordinary skill in the art would recognize that a reflective surface would reflect light that is not attenuated or absorbed.

In regards to claim 4, Sheppard, Jr. et al teach that platforms can comprise an optically transparent surface that permits a direct light path through the surface of the platform (i.e. light directed to the capture zone is transmitted through the optical disc), wherein the light source and detector are positioned on opposite sides of the platform

(i.e. disc being between the light source and a detector). See column 24, lines 20-26. A transparent surface inherently transmits light through the surface if the light is not attenuated or absorbed by a substance, including a cell. Therefore, although the reference does not teach the method where light directed to the capture zone and not striking a cell is transmitted, one of ordinary skill in the art would recognize that a transparent surface would transmit light that is not attenuated or absorbed.

In regards to claim 5, Sheppard, Jr. et al teach that specific binding reagents comprising a first member of a specific binding pair is provided coating a surface or detection chamber of a platform (i.e. coated with a first group of cell capture reagents). See column 10, lines 46-48.

In regards to claim 6, Sheppard, Jr. et al teach that the surface or detection chamber can be treated to provide a two-dimensional array or pattern, wherein certain areas on the surface or detection chamber are treated with a specific binding reagent and others are not in a recognizable manner (i.e. cell capture agents define a capture zone). See column 10, lines 60-63.

In regards to claim 7, Sheppard, Jr. et al teach that each of a multiplicity of specific binding reagents of distinct specificity are applied to different areas or regions of a surface or detection chamber of a platform, thereby providing a pattern of such distinct specific binding reagents on the platform (i.e. a second group of cell capture agents define a second capture). See column 11, lines 5-9.

In regards to claim 8, Sheppard, Jr. et al teach that the first and second capture zones are in one chamber, by disclosing a multiplicity of specific binding reagents of

distinct specificity are applied to different areas or regions of a surface or detection chamber (i.e. first and second capture zones are in one chamber). See column 11, lines 5-7.

In regards to claim 9, Sheppard, Jr. et al teach that specific binding reagents coated to a surface or detection chamber of a platform is intended to detect a cell expressing a cognate antigen (i.e. cell surface antigen). See column 10, lines 45-50.

In regards to claim 12, Sheppard, Jr. et al teach that the sample is driven into a binding/detection chamber (and contacts the surface coated with the specific binding reagent (i.e. directing the sample of cells into proximity with the cell capture agents), wherein the sample is incubated in the chamber (i.e. incubating the cells), and wherein the cells are bound to the chamber (allowing cells to bind to capture agents). See column 34, lines 29-45.

In regards to claim 13, Sheppard, Jr. et al teach the step of disclosing visually observing the number of cells bound to the chamber (i.e. analyzing the number of cells). See column 34, lines 44-45.

In regards to claims 14 and 30, Sheppard, Jr. et al teach that particles adsorbed to the surface of the waveguide will both scatter and absorb light, and that the amount of radiation transmitted to the detector that is depressed relative to clean waveguides can be used to infer the number of adsorbed particles (i.e. detecting sufficiently large changes in a level of light transmitted through the disc). See column 23, lines 15-20 and column 24, lines 50-54.

In regards to claims 15, 21 and 31, Sheppard, Jr. et al teach that visual inspection of the reaction chamber can be used to resolve cells by a computer-aided vision system (i.e. image recognition) and that preferred embodiments include detecting and quantitating individual particles, preferably cells (i.e. count captured cells in each of the capture zones). See column 32, lines 30-35 and 40-43.

In regards to claim 17, Sheppard, Jr. et al teach that arrays can be discrete arrays each comprising a different specific binding reagent (i.e. each capture zone having a different cell capture agent). See column 11, lines 9-12.

In regards to claim 18, Sheppard, Jr. et al teach that the rotation speed of the invention is increased to drive a milk sample into the binding/detection chamber, where it contacts the surface coated with the specific binding reagent and the sample is incubated in the chamber for 30 minutes (i.e. rotating for a sufficient period of time at a sufficient speed so that the cells have an opportunity to bind with capture molecules). See column 34, lines 29-32. In addition, since Sheppard et al teach that following incubation, the rotation rate is "increased", which inherently implies that there was rotation during the incubation period and therefore, the rotation period during the 30 minutes incubation was to apply a sufficient period of time at a sufficient speed so that the cells have an opportunity to bind with the capture molecules.

In regards to claims 19-20, Sheppard, Jr. et al reference teaches that the step of increasing the rotation rate after incubation so that a wash buffer flushes the milk sample out of the chamber and into the waste receptacle (i.e. rotating for a sufficient period of time at a single speed sufficient so that unbound cells are moved away from

the capture zones). See column 34, lines 32-37. In addition, the reference also teaches that after removal of the milk sample, a binding assay is performed on cells bound to the disc. See column 34, lines 37-47. Although Sheppard, Jr. et al reference does not explicitly teach the limitation of "rotating for a sufficient period of time", a certain time period of rotation is necessarily required in order to completely remove unwanted materials, including unbound cells, from the capture zone since instantaneous removal is not technically possible. In addition, a minimal rate of rotation is necessarily required in order to effectively remove liquid samples from a chamber in a disc, including unbound cells from the capture zones. Since Sheppard, Jr. et al reference teaches a binding assay performed after removal of milk sample through rotation, a "sufficient speed" is necessarily required to have been applied to remove unbound cells in order to perform the binding assays on immobilized cells.

With regards to claim 37, since Sheppard, Jr. et al teach that there is an optically transparent glass surface over the platform, any light that hits the reflective material must also go through the glass surface. See column 8, lines 5-8; column 16, lines 7-8; and Figure 1C. Therefore, the combination of the glass surface and reflective material is considered to be one embodiment that would read on the limitation of "trigger mark is a window in the disc".

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 10-11 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheppard, Jr. et al (USP 6,143,247) in view of Sizto et al (USP 5,962,238).

Sheppard, Jr. et al reference has been disclosed above, but fails to teach that the cell surface antigen is selected from the CD family of antigens.

Sizto et al reference discloses the step of determining the number of cells, including CD4 and CD8 antigens, and obtaining CD4/CD8 T-cell ratios, in order to determine the presence of cells within a particular subclass per unit volume in a sample, and to determine the progression of AIDS. See column 6, lines 17-33.

It would have been obvious to modify the method of Sheppard, Jr. et al with the step of determining the number of cells, including CD4 and CD8 antigens, and obtaining CD4/CD8 T-cell ratios, as taught by Sizto et al, in order to determine the presence of

cells within a particular subclass per unit volume in a sample, and to determine the progression of AIDS. The step of Sizto et al provides the advantage of detecting the presence of a specific subclass of cells and determining the progressing of AIDS using the method of Sheppard, Jr. et al. In addition, one of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in detecting CD4 and CD8 cells, as taught by Sizto et al, in the method of Sheppard, Jr. et al, since Sheppard, Jr. et al teach the detection and quantification of cells, and determining the number of CD4 and CD8 cells is one example of detecting and quantifying cells.

10. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sheppard, Jr. et al (USP 6,143,247) in view of Miller et al (USP 4,307,367).

Sheppard et al reference has been disclosed above, but fails to teach the method of using image recognition to distinguish one type of white blood cell from another.

Miller et al teach that pattern recognition can be used to determine a white blood cell differential count, which detects cell types, in order to determine the health of a person whose blood sample is being examined. See column 1, lines 25-29.

It would have been obvious to one of ordinary skill in the art at the time of the invention to include in the method of Sheppard, Jr. et al, the method of using image recognition to determine a white blood cell differential count which detects cell types, as taught by Miller et al, in order to determine the health of a person whose blood sample is being examined. The image recognition method of Miller et al provides the advantage of being able to clinically determine the health of a person by applying the

image recognition to the method of Sheppard, Jr. et al. One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in using image recognition to determine a while blood cell differential count, as taught by Miller et al, in the method of Sheppard, Jr. et al, since Sheppard, Jr. et al teach that computers with image processing and a computer-aided vision system can be used to resolve cells, and the pattern recognition taught by Miller et al is one example of image processing.

11. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sheppard, Jr. et al (USP 6,143,247) in view of Oflenloch-Hahnle et al (US 5,212,063) and Van der Merwe et al (US 4,478,946).

Sheppard, Jr. et al reference has been disclosed above, and additionally teaches that the specific binding reagent on the disc surface is an antibody (i.e. first antibody). See column 16, lines 18-20. However, Sheppard, Jr. et al fail to teach a first layer of streptavidin, a second layer over the first layer, the second layer comprising a first antibody raised in a first species against a type of immunoglobulin of a second species, and a third layer over the second layer, the third layer comprising a second antibody raised in the second species against a cell surface antigen.

Oflenloch-Hahnle et al reference teaches a surface coated with streptavidin, in order to immobilize an antibody to a solid phase, wherein the antibody is biotin-labeled. See column 8, lines 25-48.

Van der Merwe et al reference teaches a double layer with sheep IgG antibodies in a first layer raised against rabbit IgG, and a second layer of rabbit IgG specific

against an antigen, in order to provide a means for orienting the second layer outward from the substrate. See column 5, lines 17-19 and column 10, lines 40-52.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Sheppard, Jr. et al with a surface coated with streptavidin, as taught by Oflenloch-Hahnle et al, in order to immobilize an antibody to a solid phase, wherein the antibody is biotin-labeled, and with a double layer with sheep IgG antibodies in a first layer raised against rabbit IgG, and a second layer of rabbit IgG specific against an antigen, as taught by Van der Merwe et al, in order to provide a means for orienting the second layer outward from the substrate. The streptavidin of Olfenloch-Hahnle et al and the double antibody layer of Van der Merwe et al provide the advantages of solid phase antibody immobilization and antibody orientation in the microfluidic device of Sheppard, Jr. et al. In addition, one of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including a streptavidin-coated surface, as taught by Oflenloch-Hahnle et al, and including a double layer of antibodies, as taught by Van der Merwe et al, in the method of Sheppard, Jr. et al, since Sheppard, Jr. et al teach solid phase immunoassays, and the antibody double-layer and streptavidin-coated surfaces are also applied to solid phase immunoassays.

12. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sheppard, Jr. et al (USP 6,143,247) in view of Mian et al (US 6,319,469 B1) and Christian (US 4,673,657).

Sheppard, Jr. et al reference has been disclosed above, but fails to teach a control and that the capture zones are located in a fluid path between the inlet port and the vent port.

Mian et al reference teaches air outlet ports 29 and 33-35, wherein outlet 29 is farther down the fluid flow from the center inlet and reaction chambers 16, 22, and 24, in order to provide a means for fluids to displace air and ensure uninhibited movement of fluids on the disk. See column 3, lines 36-57; column 4, lines 47-52; and Figures 1A-C.

Christian reference teaches positive and negative controls, in order to aid in quantitation and detect false negatives or positives. See column 13, lines 41-49.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Sheppard, Jr. et al with air outlet ports 29 and 33-35, wherein outlet 29 is farther down the fluid flow from the center inlet and reaction chambers 16, 22, and 24, as taught by Mian et al, in order to provide a means for fluids to displace air and ensure uninhibited movement of fluids on the disk, and with positive and negative controls, as taught by Christian, in order to aid in quantitation and detect false negatives or positives. The outlet ports of Mian et al provide the advantage of allowing uninhibited movement in the microfluidic channels of Sheppard, Jr. et al, and the positive and negative controls of Christian provide the advantage of detecting false negatives or false positives using the microfluidic platform of Sheppard, Jr. et al. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including air outlet ports down the fluid flow from a center inlet and reaction chambers, as taught by Mian et al, and including positive and negative

controls, as taught by Christian et al, in the method of Sheppard, Jr. et al, since

Sheppard, Jr. et al also teach air vents and serial placement of different capture zones.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 1-22 and 30-37 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 and 13-46 of copending Application No. 10/233,322 and in view of Sheppard, Jr. et al (USP 6,143,247).

Claims 1-22 and 30-33 of the instant application disclose a method of conducting an assay, the method comprising providing a sample of cells in a chamber in a disc, the chamber including at least one capture zone with a capture agent, the disc including at least one inlet port and a vent port on a first surface of the disc, loading the disc into an optical reader which includes a detector and a trigger sensor, rotating the disc so as to

capture different cell types in different capture zones, directing an incident beam of electromagnetic radiation to the at least one capture zone, detecting by use of the detector at least one beam of electromagnetic radiation formed after interacting with the disc at the at least one capture zone, detecting trigger information by use of the trigger sensor from a disc location that is separate from the at least one capture zone, wherein the disc includes information for controlling the rotation of the disc and information for processing the specific immunotyping assay to be conducted, generating a trigger signal in response to the detected trigger information, generating an output signal indicative of at least a portion of the at least one beam relating to captured cells, processing at least a portion of the output signal in response to the trigger signal, analyzing the at least a portion of the output signal to extract therefrom information relating to the number of cells captured at the at least one capture zone, generating a count of the number of cells in each of the at least one capture zones, and providing an output including the counts.

Claims 1-10 and 13-46 of the copending application disclose all of the limitations of the instant application with the exception of the disc including at least one inlet port and a vent port on a first surface of the disc, an optical reader includes both a detector and a trigger sensor, rotating the disc so as to separate different cell types into different capture zones, detecting trigger information by use of the trigger sensor from a disc location that is separate from the at least one capture zone, wherein the disc includes information for controlling the rotation of the disc and information for processing the specific immunotyping assay to be conducted, generating a trigger signal in response to

the detected trigger information, and processing at least a portion of the output signal in response to the trigger signal.

Sheppard, Jr. et al reference teaches a platform with sample input means, air displacement vents, multiple detectors that perform optical functions including detecting multiple beams focused on either the main beam illuminating cells on an upper surface or secondary beams illuminating reflective regions, detection chambers that can be arrayed serially with a pattern of distinct specific binding reagents therein, including concentric circles and "bar codes", and including controllers fabricated directly onto a platform use data encoded in the disk's data-carrying surface can be used to control the rotation drive and analysis, wherein the platform can be spun, and wherein the number of cells on the platform can be processed, in order to simultaneously perform tracking of the disc and identify particular cells or cell types in a biological sample. See column 3, lines 29-38; column 8, lines 9-14; column 11, lines 1-25 and 40; column 12, lines 15-35; column 21, lines 57-67; column 26, lines 55-56; column 26, line 63 to column 27, line 11; column 27, lines 24-27; and Figure 1D and Example 1.

Although Sheppard, Jr. et al reference does not explicitly teach rotating the disc so as to separate different cell types into different capture zones, the instant reference teaches the instant limitation by disclosing disc rotation and a series of binding reagent arrangements, as stated above. The instant reference discloses a multiplicity of specific binding reagents in different areas of a detection chamber, the arrangement of a "bar code" or concentric circles in a detection chamber, and the placement of multiple detection chambers in a serial array. Since the reference teaches rotation of the disc,

centrifugal force would move sample fluid in a serial fashion, causing the fluid to enter the serially arrayed detection chambers in a sequential manner. Cell types in a fluid sample would be captured by the distinct specific binding reagents in different regions of the disc, either in the detection chambers or in different regions of the "bar code" or concentric circles within a detection chamber, thereby separating cell types into different capture zones.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of the copending application with a platform with sample input means, air displacement vents, multiple detectors that perform optical functions including detecting multiple beams focused on either the main beam illuminating cells on an upper surface or secondary beams illuminating reflective regions, detection chambers that can be arrayed serially with a pattern of distinct specific binding reagents therein, including concentric circles and "bar codes", wherein the platform can be spun, and wherein the number of cells on the platform can be processed, as taught by Sheppard, Jr. et al, in order to simultaneously perform tracking of the disc and identify particular cells or cell types in a biological sample. The teaching of Sheppard, Jr. et al provides the advantage of allowing both cell detection and spatial tracking in the method of the copending claims. In addition, one of ordinary skill in the art at the time of the invention would have reasonable expectation of success in rotating the disc to separate cells, as taught by Sheppard, Jr. et al, in the method of the copending claims since both the copending claims and Sheppard, Jr. et al teach a rotating optical disk for detecting and counting cells.

Response to Arguments

15. On pages 7-8 of the Remarks, Applicants traverse the rejection of claims 1-9, 12-15, 17-21, 30-31, and 34-37 under 35 U.S.C. 102(e) as being anticipated by Sheppard, Jr. et al (US 6,143,247) by arguing that Sheppard does not teach a disc that includes information for controlling the rotation of the disc and information for processing the specific immunotyping assay to be conducted, as recited in claim 1(see page 8, 1st full paragraph).

Applicant's arguments have been fully considered but they are not persuasive. As indicated in the rejection supra, Sheppard teaches that the disks can have data encoded in the disk's data-carrying surface that can be used to control the rotation drive motor and analysis. The disclosure of a disk that includes information that controls the disk rotation directly anticipates the claimed limitation of a disc that includes information for controlling the rotation of the disc. The disclosure of a dish that has encoded data to control analysis directly anticipates the claimed limitation of a disc that includes information for processing the specific immunotyping assay to be conducted. The term "analysis" in Sheppard can be applied to read on the claimed limitation "processing the specific immunotyping assay to be conducted" since the specification does not define the term "processing", and an "analysis" in the context of the platform immunoassays of Sheppard (see column 33, lines 14-15) is considered to be the same as the claimed processing of an immunoassay.

Therefore, since Sheppard teaches each and every limitation of claim 1, Applicant's arguments are not found convincing and the rejection set forth in the previous Office Action is maintained.

Conclusion

16. No claims are allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y. Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on weekdays from 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leon Y. Lum
Patent Examiner
Art Unit 1641

LYL

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

10/31/05